

BEFORE THE IOWA BOARD OF PHARMACY

RE: Limited Use Pharmacy License of HY-VEE CLINIC PHARMACY 3028 License No. 1200 Respondent	CASE NO. 2018-139 COMBINED STATEMENT OF CHARGES, SETTLEMENT AGREEMENT, AND FINAL ORDER
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COME NOW the Iowa Board of Pharmacy ("Board") and Hy-Vee Clinic Pharmacy 3028 ("Respondent"), 321 N Main St, Marcus IA 51035, and enter into this Combined Statement of Charges, Settlement Agreement, and Final Order ("Order") pursuant to Iowa Code sections 17A.10 and 272C.3(4), and 657 IAC 35.5. The Board has jurisdiction over Respondent and the subject matter of this case pursuant to Iowa Code chapters 17A, 155A, and 272C (2018), and 657 IAC chapter 36.

A. STATEMENT OF CHARGES

COUNT I

FAILING TO COMPLY WITH MONTHLY INSPECTION REQUIREMENTS

1. Respondent is charged with failing to maintain monthly inspection reports as mandated by 657 IAC 13.9(5) and 13.23(4), and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

COUNT II

FAILING TO COMPLY WITH PERPETUAL INVENTORY REQUIREMENTS

2. Respondent is charged with failing to comply with the perpetual controlled substances inventory requirements of 657 IAC 13.9(10), and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

COUNT III

FAILING TO PROPERLY RECORD PSEUDOEPHEDRINE SALES

3. Respondent is charged with failing to record the name or unique identification of the individual who approved dispensing of a pseudoephedrine product in violation of 657 IAC 100.3(1)"f", and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

COUNT IV

FAILING TO COMPLY WITH SECURITY REQUIREMENTS

4. Respondent is charged with failing to have an electronic keypad or other electronic entry system into the telepharmacy site or the pharmacy department that requires and records the unique identification of the individual accessing the pharmacy in violation of 657 IAC 13.8(3)"a", and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

COUNT V
FAILING TO TIMELY NOTIFY OF PIC CHANGE

5. Respondent is charged with failing to notify the board of the temporary pharmacist in charge within ten days of a vacancy in violation of 657 IAC 8.35(6)"d" and 13.17(1), and may be disciplined pursuant to Iowa Code section 155A.15(2)(c) and 657 IAC 36.6(21).

B. FACTUAL CIRCUMSTANCES

6. Respondent began operating as a telepharmacy site in Marcus in May 2018. Respondent is managed by Hy-Vee Pharmacy 1068.

7. In November 2018, Respondent underwent a routine inspection which revealed the following deficiencies:

- a. Neither Respondent nor the managing pharmacy had records available for the required monthly inspections. The monthly inspection records were available at a later date at the telepharmacy site.
- b. Some of the monthly inspection records did not show monthly audits of the electronic entry system.
- c. Some of the monthly inspection reports did not show verification of proper function and retention of the video recording system.
- d. Audit and reconciliation of controlled substances perpetual and physical inventories was not being performed monthly.
- e. Incident reporting for changes to the perpetual inventory was not being properly utilized.
- f. Records for pseudoephedrine sales were not recorded using the unique identification for the individual making the sale.
- g. Records of access to the pharmacy did not include unique identification of the individual accessing the pharmacy.

8. On October 16, 2018, Respondent's pharmacist in charge vacated the position. Respondent did not notify the Board of a temporary pharmacist in charge until October 30, 2018.

C. SETTLEMENT AGREEMENT AND FINAL ORDER

9. The Board has jurisdiction over the parties and the subject matter of this proceeding.

10. Respondent acknowledges that the allegations in the Statement of Charges, if proven in a contested case hearing, would constitute grounds for the discipline agreed to in this Order.

11. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.

12. Respondent acknowledges that it has the right to be represented by counsel on this matter.

13. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.

14. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.

15. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

16. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank.

17. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

18. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

19. Respondent's license is hereby placed on **PROBATION** for a period of two (2) years, subject to the following terms:

- a. Within thirty (30) days of this Order, Respondent shall pay a civil penalty in the amount of five thousand dollars (\$5,000). The check shall be made payable to the "Treasurer of Iowa" and shall be deposited in the general fund. The civil penalty should be mailed to the Iowa Board of Pharmacy, Attn: Amanda Woltz, 400 SW 8th St, Ste E, Des Moines IA 50309.
- b. Within thirty (30) days of this Order, Respondent shall designate a new proposed managing pharmacy. The proposed managing pharmacy must not be currently subject to any disciplinary sanctions. Within one hundred and twenty (120) days of this Order, Respondent shall transition to being managed by the newly designated managing pharmacy.

- c. Respondent shall designate a pharmacist who is primarily responsible for performing the monthly inspections and overseeing compliance of the telepharmacy site. Respondent shall update its monthly inspection checklist template to clearly identify who is responsible for each aspect of the monthly inspection and to clearly describe the task to be performed as part of the monthly inspection. The updated monthly checklist template shall be reviewed and approved with signature by the designated pharmacist, the pharmacist in charge, and all telepharmacy technicians. Respondent shall submit the name of the designated pharmacist, the updated monthly inspection checklist, and signed approvals to the Board within thirty (30) days.
- d. A copy of each monthly inspection checklist, along with supporting documentation, shall be submitted to the Board by the 7th day of the month following the month of inspection (e.g., January inspection documentation shall be submitted to the Board no later than February 7th).
- e. Respondent shall notify the Board within three (3) business days of any change in the designated pharmacist or pharmacist in charge.
- f. Respondent shall be staffed by a pharmacist for at least twenty-four (24) hours per month while on probation.
- g. Respondent shall appear before the Board upon request for purposes of evaluating performance of the probationary period. Respondent shall be given reasonable notice of the date, time, and place for such appearances.
- h. Respondent shall abide by all state and federal laws and regulations governing the practice of pharmacy. Respondent shall operate in accordance with its policies and procedures.
- i. Any documentation required to be submitted shall be emailed to Amanda.Woltz@iowa.gov by the specified deadline unless otherwise directed.

20. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 155A and 272C and 657 IAC chapter 36.

By the signature below, Kristin Williams acknowledges s/he is the Senior Vice President, Chief Health Officer for Respondent and is authorized to sign this Combined Statement of Charges, Settlement Agreement, and Final Order on behalf of Respondent.

3/11/2019
Date

AK Williams
HY-VEE CLINIC PHARMACY 3028
Respondent

This Combined Statement of Charges, Settlement Agreement, and Final Order is approved by the Iowa Board of Pharmacy on the 12th day of March, 2019.

Sam Merg
Chairperson
Iowa Board of Pharmacy